Washington State Department of Health

# ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume VII Issue 10 November/December 2002

# Laboratory Conference Highlights

by Leonard Kargacin

Dennis Weissman presented the keynote address for the 9th Annual Clinical Laboratory Conference that was held on November 11, 2002, in Seattle. His presentation was titled "National Policy Priorities & Trends for Laboratories: Taking Stock of the Midterm Elections". The following is a synopsis of this presentation.

**2002 election analysis:** Both Houses of the 108th Congress that begins in January 2003 will be under Republican control. Three major agendas the Republicans are going to push:

- Medicare prescription drug benefit under a privately run system that will allow the pharmaceutical companies to set the rates for the drugs with some subsidization for people who can't afford drugs
- Cap medical malpractice suits
- Tax credit for the uninsured

**Lame Duck Session of the 107th Congress:** The most immediate concern for the laboratory is what is going to happen in this lame duck session of the 107th Congress. None of the bills pending in Congress would change the laboratory CPI update scheduled for January 1, 2003. The CPI is still being determined, but is anticipated to be around 1.5%.

The following legislation is not expected to be acted upon by the lame duck session of Congress:

- Medicare prescription drug coverage (will be addressed in the 108th Congress)
- Dunn/Hatch Laboratory Testing Act (HR 1798/S 1066)
- Annual Pap Smear coverage
- Specimen collection fee (HR 3388) raising Medicare fee from $3 to $5.25 (will probably be addressed in the 108th Congress)
- Medical Laboratory Personnel Shortage Act (HR 1498)
- HR 1451/S 730 allows independent laboratories to globally bill for inpatient and outpatient anatomic pathology services if the lab/hospital agreement was in effect since 7/22/99. Unless this is passed by the lame duck session, effective January 1, 2003 hospitals will have to start billing for anatomic pathology services even if an outside laboratory performs the work for inpatients and outpatients.

**Medicare Bills**

House passed Medicare Bills:

- Contains a 1-year extension of the grandfather provision applied to the technical component (TC) billing for Medicare for inpatients and outpatients. If the extension passes this year it may allow the extension to continue until the GAO study to determine if this provision should be made permanent is completed.
- Requires development of a process for setting Medicare rates for innovative diagnostic tests (part of the Dunn Bill HR 1798).

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## Inside This Issue



## Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

- Anemia
- ANA
- Bioterrorism Event Mgmt
- Bleeding Disorders
- Chlamydia
- Diabetes
- Group A Strep Pharyngitis
- Hepatitis
- HIV
- Intestinal Parasites
- Lipid Screening
- Point-of-Care Testing
- PSA
- Renal Disease
- STD
- Thyroid
- Tuberculosis
- Urinalysis
- Wellness

# Conference Highlights, continued from page 1

- Eliminates the Medicare secondary payer screening requirements for hospital reference laboratory tests.
- Includes a competitive bidding demonstration project for Medicare Part B laboratory services that do not involve face-to-face encounters between the patient and hospital or ordering doctor.

Senate pending Medicare legislation:
- Includes $41 billion over 10 yeats to increase Medicare reimbursement for physicians, hospitals and other institutional providers, and Medicare+Choice plans.
- Extends for three years the current grandfather provision that allows independent labs to continue to bill Medicare for the professional component (PC) component of anatomic pathology services to hospital inpatients and outpatients.
- Requires a competitive lab bidding demonstration with a report due by December 31, 2004. Since both the House and Senate versions have this provision, there is a possibility that it will be passed by this lame duck session.
- Covers diagnostic testing for early detection of elevated cholesterol and blood lipids.
- Improves thin prep Pap test payment for a 2-year period up to 100% of the national fee cap (not in House version).

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- Extends for two years, the Medicare payment of 100% of reasonable costs for diagnostic lab tests in sole community hospitals with no beneficiary cost-sharing. This is an existing provision. This extension might get through since it has a lot of support.

There is no assurance what Congress will do in this lame duck session. They must pass a stop-gap spending bill because none of the federal departments have final appropriations for fiscal year 2003. A compromise version of the House and Senate Medicare bills might be added as an amendment under the spending bill, otherwise, there will not be enough time to get it through as a free-standing bill.

**Laboratory Regulatory Agenda**

**New Advanced Beneficiary Notice (ABN):** The Centers for Medicare & Medicaid Services (CMS) finalized two standardized ABN formats: CMS-R-131-L for laboratory services only, and CMS-R-121-G for general use. CMS issued final instructions on the use of the new standard ABN forms in August. Laboratories can continue to use the old form until the new formats become effective on January 1, 2003. The forms may be downloaded from the CMS website: http://cms.hhs.gov/medicare/bni/.

**Lab Coverage Policies:** Health and Human Services (HHS) issued the final rule covering national Medicare Part B uniform coverage policies for 23 frequently performed lab tests (60-70% of total payments for Part B laboratory services). The rule clarifies or codifies documentation and record keeping requirements plus claims review procedures to be used by Medicare contractors. Local Medicare carriers and intermediaries must follow national policies for the 23 tests covered. The rule:
- Becomes effective November 25, 2002, except for certain administrative changes that were effective February 21, 2002.
- Specifies the specimen collection date as the date of service.
- Requires that the contractor contact the doctor directly to obtain missing medical documentation before denying the claim; but if doctors do not provide the documentation, they are still not subject to Medicare sanctions.
- Allows labs and contractors to apply to CMS (by November 25, 2002) for a delay of up to 12 months in adopting any requirements that necessitate computerized changes.

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# Conference Highlights, continued from page 2

- Requires notice in writing to CMS 90 days before the effective date of provisions that cannot be implemented on time.
- Does not require physician signature on the test requisition.
- Allows for labs to assign an appropriate diagnosis code to narrative diagnosis written by the provider.
- Specifies that contractor may not use frequency screens to deny claims without published guidance explaining what is reasonable utilization for Medicare claims payment.
- Allows the use of the narrative field on the claim form to report additional diagnosis when required.
- Requires that Medicare contractors review all claims data and relevant documentation before the test can be denied.

**Stark II Final Rule (Phase I)** prohibits referring Medicare/Medicaid patients to facilities where the physician or their immediate family member has a financial or compensation relationship. Phase I was effective on January 4, 2002. Phase II (final rules have not yet been published) covers a long list of designated health services including hospitals and lab services. It clarifies that labs cannot give physician clients such items as gloves and biopsy needles, but can provide physician clients single-use needles, vials and specimen cups based on the number of specimens referred. Exempted are requests by pathologist for lab/path services if furnished by, or under supervision of, the pathologist pursuant to a consultation requested by another MD.

**CLIA Policy Changes**

- Revised QA/QC standards are expected to be out by the end of 2002.
- CMS is still concerned about the quality of waived testing performed (will survey 2% of waived labs).
- New genetic testing standards are not expected until 2003/2004, if at all.

**Office of the Inspector General (OIG):** The OIG is now focusing on quality of life issues in nursing homes and home health care. For laboratories, they are tending to look at whether or not you are actually doing tests that are allowed under your CLIA license.

# Laboratory-Based Practice Gudelines

by Leonard Kargacin

A critical area of concern in the current cost-conscious health care environment is optimization of service delivery. Over-utilization of laboratory testing can lead to needless and costly treatment for the patient. Under-utilization can result in a misdiagnosis and delays in treatment. To address inappropriate or unnecessary use of laboratory testing services, the Clinical Laboratory Advisory Council decided to establish a process for developing practice guidelines for clinical laboratory testing. The guidelines are for educational purposes only.

The intent of the guidelines is to help laboratorians answer questions they may get from clinicians on appropriate test ordering. The guidelines will also be useful to clinicians as a review of a typical test-ordering pattern for patients. The guidelines are a compilation of existing data, not original work by the Council. For the format, the Council elected to summarize existing information into simple, easy-to-use flow charts. Once a test has been identified by the Council as a candidate for a guideline, a Council workgroup is formed to develop a proposed guideline. The draft guideline is reviewed by the entire Council, members of the state's laboratory community and appropriate medical professional societies. Comments from the reviewers are evaluated by the Council workgroup and incorporated into the final document. The finalized guideline is disseminated to all clinical laboratories and other interested parties through this newsletter.

**FOR EDUCATIONAL PURPOSES ONLY**

**The guidelines should be used strictly as guidelines. The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.**

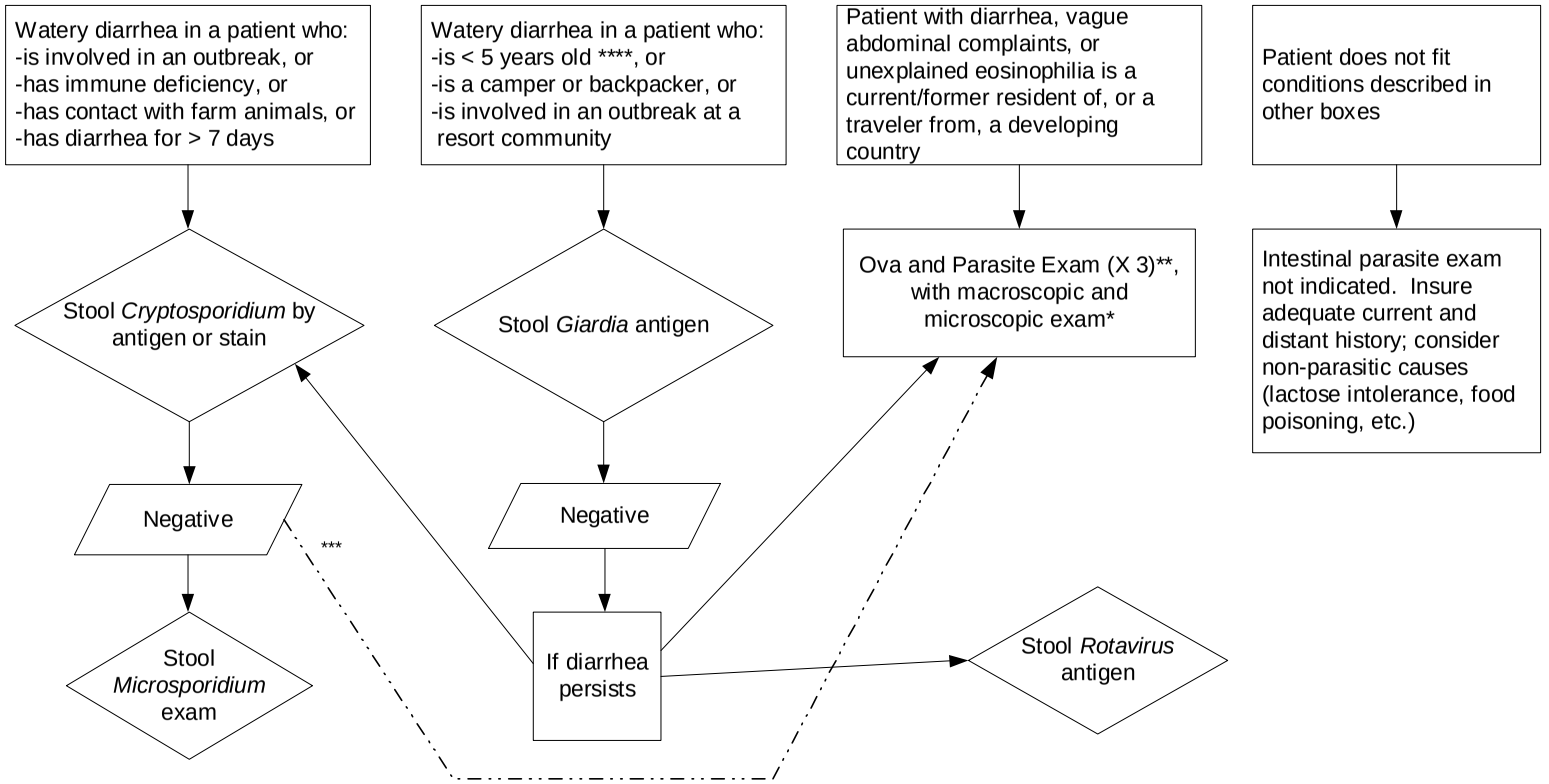
Guidelines developed by the Council that have been previously published in E**LAB**ORATIONS are listed in a box on the front page ot this newsletter. This issue of E**LAB**ORATIONS contains the Group A *Streptococcus pyogenes* Pharyngitis guideline and the guideline for Intestinal Parasites.

# Laboratory Guidelines For Intestinal Parasites

Suggested Physician Ordering Plan for the Laboratory Examination Of Stool Specimens
Washington State Clinical Laboratory Advisory Council
October 2002

**FOR EDUCATIONAL PURPOSES ONLY**
The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.

## Patient Characteristics




**NOTES:**

* If negative, consider adding Giardia Antigen test because of greater sensitivity.
** Collect every other day or 3 samples over 10 days
*** Perform O&P exam to look for Cyclospora and Isospora. Some labs perform at same time asCryptosporidium
**** For < 5 years old, consider ordering Rotavirus antigen as part of initial work up

**References:**

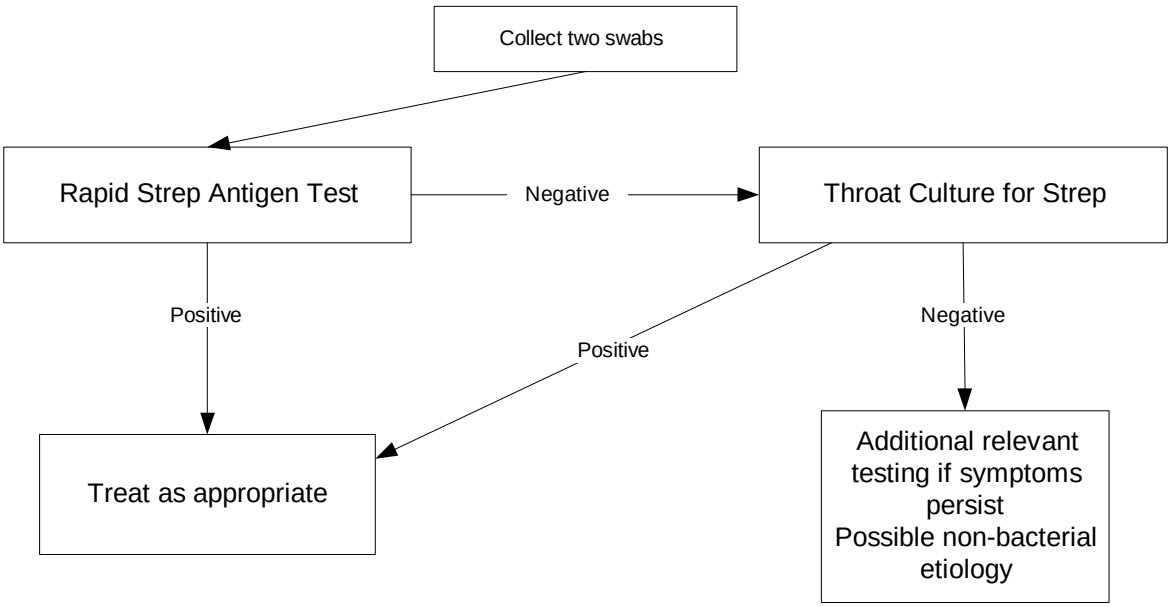
1. Personal communication Joseph Yao, MD; Mayo Clinic
2. Personal communication Brad Jensen, MD; SWMC Vancouver, WA
3. Mayo Clinic Reference Laboratory Manual
4. Shirley Phillips, PhD, letter dated 1/21/1995; Legacy Laboratories

# Group A *Streptococcus pyogenes* Pharyngitis Guidelines

Washington State Clinical Laboratory Advisory Council
October 2002

**FOR EDUCATIONAL PURPOSES ONLY**
The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.

**Patient Characteristics:**
- Sudden onset of sore throat
- Tonsillitis with or without exudate
- Tender anterior cervical adenopathy
- History of fever, headache and/or abdominal pain




**NOTES:**
1. Routine culturing for asymptomatic family members are not indicated unless:
   a. History of Rheumatic Fever;
   b. "Ping Pong" spread of Group A Strep has been occurring within the family.
2. Other organisms such as Group C Strep, Group G Strep, and*Arachanobacterim haemolyticum* also can cause acute bacterial pharyngitis and are also beta hemolytic.

REFERENCES:
1) Diagnosis & Management of Group A Streptococcal Practice Guideline. Clinical Infectious Disease 1997 Spt 27(3): 574-83.
2) Acute Pharyngitis. Institute for Clinical Systems Improvement; 2000 June 24.
3) Pharyngitis (in adults and children). University of Michigan Health System: 1996 8p.
4) Acute Pharyngitis, Bisno, A.L., 2001 NETM, 344(3):205-11.

# Waived Testing Helpful Hints

In the last issue, we discussed Good Laboratory Practice (GLP) #2: Label and store the specimen properly. Here is GLP #3: Check kit expiration date.

√ Do not use kit beyond the expiration date.

√ Store the kit as directed in the package insert.

√ If the kit can be stored at room temperature but this changes the expiration date, be sure to write the new expiration date on the kit.

√ Do not mix reagents from different kits.

**NOTE:** Check this spot in future editions of Elaborations for more helpful hints with waived testing.

## Calendar of Events

**PHL Training Classes:**

Blood Parasites
January 8-9 Shoreline

Shipping & Handling Biohazad Materials
February 12 Shoreline

Patasitology Part II: Protozoans
February 26-27 Shoreline

**WSSCLS/NWSSAMT Spring Meeting**
April 24-26 Pasco

**Northwest Medical Laboratory Symposium**
October 22-25 Olympia

**10th Annual Clinical Laboratory Conference**
November 10 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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